Cat. No 9-429

DIAGNOSTIC KIT FOR DETERMINATION OF IgA CONCENTRATION

OS – IgA

INTRODUCTION
Immunoglobulins (Igs) are the instrumental proteins of immunity. Immunity is a property of the lymphoid system which is made of organs (spleen, thymus, bone marrow) and of cells (lymphocytes). Circulating immunoglobulins are secreted in the blood by B lymphocytes and they thereby export far-away the specific biological functions of humoral immunity. Immunoglobulin A (IgA) is the major Ig found in secretions, playing a major role in the protection of the respiratory, genitourinary, and gastrointestinal tracts against infection.

METHOD PRINCIPLE
The IgA present in a sample form with the specific antibody an immunological complex. The increase of turbidity after the addition of antiserum is proportional to IgA concentration in the sample.

REAGENTS
Package

1-Reagent	1 x 44.5 ml
2-Reagent	1 x 10.5 ml

Buffer (1-Reagent) stored at 2-25°C and antiserum (2-Reagent) stored at 2-8°C are stable until expiry date printed on the package. Protect from light and avoid contamination!

Concentrations in the test
Tricine buffer (pH 8.0); PEG; sodium chloride; anti human IgA antiserum; HEPES buffer (pH 7.4); stabilizers.

Warnings and notes
- Products for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Products from human source have been tested for the HBsAg and antibodies to HIV and HCV and found to be non-reactive. However this material should be handled as thought capable of transmitting infectious disease.
- Products contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN
Serum.
Specimen without lipemia or hemolysis is recommended.
Specimen can be stored up to 3 days at 2-8ºC or up to 6 months at -20ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE
These reagents may be used in automatic analysers Olympus AU400/AU640.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION
Reagent ID: **044**

Specific Test Parameters

General | LIH | ISE | Range

Test name: **IgA** Type: **Serum** Operation: **Yes**

Sample: Volume	2.5	µL	Dilution	0	µL	Pre-Dilution Rate:	1	
Reagents: R1 Volume	200	µL	Dilution	0	µL	Min OD	Max OD	
R2 Volume	40	µL	Dilution	0	µL	L -2.0000	H 2.5000	
						Reagent OD Limit:		
Wavelength: Pri.	570		Sec.	800		First L -2.0000	First H 2.5000	
Method:	END					Last L -2.0000	Last H 2.5000	
Reaction Slope:	+					Dynamic Range:		
Measuring Point 1: First	0		Last	27		L	H	
Measuring Point 2: First	0		Last	10		Correlation Factor:		
Linearity:		%				A 1.000	B 0.000	
No-Lag-Time:						On-board Stability Period:		

Specific Test Parameters

General | LIH | ISE | Range

Test name: **IgA** Type: **Serum**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7.	None Selected					#	#
8	Out of Range					#	#

	L	H		
Panic Value:	#	#	Unit: g/l	Decimal Places: 2

Calibration Specific

General | ISE

Test name: **IgA** Type: **Serum**

Calibration Type: **6AB** Formula: **Spline** Counts: **1** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:	#		*	-2.0000	2.5000
Point 4:	#		*	-2.0000	2.5000
Point 5:	#		*	-2.0000	2.5000
Point 6:	#		*	-2.0000	2.5000
Point 7:					

1-Point Cal.Point: with CONC-0 Slope Check: **None** Advanced Calibration: #

MB Type Factor: Calibration Stability Period:

\# User defined
* Calibrator value
** Saline should be used as calibrator 1

REFERENCE VALUES [4]

adults	0.40 – 3.50 g/l
children (1 year – 12 years)	0.15 – 2.50 g/l
children (1 month – 12 months)	0.20 – 0.90 g/l

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL
For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL III (Cat. No 4-291) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY IMMUNO-MULTICAL (Cat. No 4-287) is recommended.
The calibration curve should be prepared every 4 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analysers Olympus AU400, Cobas Mira and Hitachi 911. Results may vary if a different instrument is used.

- **Measurement range:** 0.02 g/l to 8 g/l.

- **Specificity / Interferences**
  Haemoglobin up to 0.32 g/dl, bilirubin up to 29.5 mg/dl, triglycerides up to 1000 mg/dl, heparin up to 0.5 g/l, sodium fluoride up to 4 g/l, EDTA up to 5 g/l, sodium citrate up to 5 g/l do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	123.1	1.6	1.3
level 2	214.8	2.2	1.0
level 3	297.2	3.2	1.1

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	117.2	4.1	3.5
level 2	220.8	5.7	2.6
level 3	300.8	8.5	2.8

- **Method comparison**

A comparison between IgA values determined at Olympus AU400 (y) and at ADVIA 1650 using 24 samples gave following results:
y = 0.8251 x + 0.0717 g/l;
R = 0.9902 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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3. Burtis C.A., Ashwood E.R., Bruns D.E., ed. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 4th ed., PA: WB Saunders., (2006).
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